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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,173

10/05/2005

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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

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DELIVERY MODE

06/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/552,173	Applicant(s) HASHIMOTO ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 June 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1,2 and 5-7.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/Kevin S. Orwig/
 Examiner, Art Unit 1611

/David J Blanchard/
 Primary Examiner, Art Unit 1643

Continuation of 11. does NOT place the application in condition for allowance because:

REJECTIONS MAINTAINED:

The arguments presented by applicants are unpersuasive for at least the following reasons.

Claims 1, 2, and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over TSURUDA (International Publication No. WO 01/68061; Published Sep. 20, 2001; Reference BA on IDS dated Oct. 5, 2005) in view of CORDES (WO 97/23227, published Jul. 3, 1997) as evidenced by TSURUDA (U.S. Patent No. 6,924,410; Issued Aug. 2, 2005).

RESPONSE TO ARGUMENTS:

Applicants argue that since the instant application claims a property of the patch measured in a way different from that of Tsuruda, the two must be patentably distinct (p. 5 and 7 of the response).

The examiner notes that merely testing a product under conditions different from those in the prior art, and claiming the same product, or an obvious variant thereof, by way of the new test conditions does not make the product patentable. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Applicants are encouraged to provide actual data comparing Tsuruda's patch preparations under the SAME UV measurement conditions as instantly claimed in order to clarify exactly how different the two patch preparations actually are by DIRECTLY comparable measurements in order to clarify this issue. No such data have been provided at this time.

Applicants argue that Tsuruda's backings were irradiated by sunlight lamps while the instant backing was irradiated under direct sunlight, and assert that the two are 'quite different'.

Applicants provide no actual evidence to support their assertion that these two methods are 'completely different'. Rather than being quite different, the two measurement methods appear to be closely related and are used for the same purpose in the art, namely to assess the phototransmission rate of the backing materials. The examiner has previously acknowledged that there is a difference between the two measurement methods (see p. 7-8 of the prior Office Action). This difference does not, of itself, impart patentable distinctness to the product. In response to applicant's argument that Tsuruda does not test the backings under the same conditions as instantly claimed, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In the instant case, Tsuruda is drawn to a patch structure that is identical to that instantly claimed. Tsuruda's patches feature the same backing materials and the same UV absorbing materials as those instantly claimed. The UV transmittance of the backing is determined by the identity of these materials, which Tsuruda discloses. Tsuruda's patches can have a transmittance of less than 2.0% under conditions related to those instantly claimed (Table 1). Further, the teachings of Tsuruda would not only motivate the ordinary artisan to reduce the UV transmittance as much as possible when using photosensitive drugs (e.g. such as ketoprofen) in the patches (see the discussion *supra*), but would also lead one to do so. Additionally, applicants have not addressed the fact that Tsuruda discloses a phototransmission rate. If this is different from the UV transmittance, then the actual UV transmittance of this light transmission is likely to be lower than the phototransmission disclosed by Tsuruda. Moreover, Tsuruda teaches the use of the same materials for the very same purpose as that instantly claimed. Thus, one of skill in the art would have had a reasonable expectation of success in reducing the UV transmittance of Tsuruda's patches by no more than routine experimentation.

It is well established that the motivation to combine may be implicit and may be found in the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *Id.* at 1366, 80 USPQ2d at 1649. "[A]n implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the improvement is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal and even common-sensical we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him capable of combining the prior art references." *Id.* at 1368, 80 USPQ2d at 1651.

In this case the artisan need not even combine references. The teachings of Tsuruda clearly teach that lowering the UV transmission of the patch is beneficial when UV sensitive drugs (e.g. ketoprofen) are used. The artisan would clearly be motivated to reduce the amount of UV transmittance based on Tsuruda's teachings, in order to obtain a patch in which NSAIDs like ketoprofen are as stable as possible, and would be capable of doing so, for example, by increasing the amount of UV absorber in the backing.

Applicants argue that the examiner was incorrect in asserting that the thickness of the backing could have resulted in the difference between Tsuruda's example 6 and instant comparative example 2 (page 6 of the response). Applicants point to instant example 2 and comparative example 2 as allegedly refuting the examiner's argument. However, whether the backings are the same in example

2 and comparative example 2 is irrelevant because the difference in UV intensity between these two examples was obviously due to the different UV absorbers used in these two examples. Thus, this argument has no bearing on the weights or thicknesses of the backing materials used.

Applicants argue certain results were achieved by the instant invention that were not disclosed by Tsuruda (3rd paragraph of p. 8 of the response).

It is noted that Tsuruda directly teaches all of the effects applicants point to as being novel (see col. 11-12 of Tsuruda, elements numbered 1-6) with the exception of the specific UV measurement conditions instantly recited. It has been noted above that measurement by a different method does not make a product patentable.

Applicants argue that Cordes does not disclose a polyester backing layer as instantly claimed.

This argument was discussed in detail in the prior Office Action, and is maintained for the reasons of record. The examiner maintains that the teachings of Tsuruda would have been sufficient in and of themselves to meet the limitation of the backing weight, as the error in Tsuruda would have been readily apparent to the skilled artisan. See the previous two Office Actions for further discussion of this matter. In any case, Cordes teaches a polyester film coated with an adhesive mixture weighing 96-98% as an intermediate liner. As stated previously, such a liner can be construed as a backing layer. Thus, the teachings of Cordes are sufficient to cure any discrepancy in Tsuruda, even in the case that one exists, which has not been demonstrated by applicants at this time due to their silence on the error in Tsuruda.

The Double Patenting rejections over U.S. Patent No. 6,924,410 are maintained in view of Cordes, since, as discussed above, the instantly claimed invention is nothing more than an obvious variant of the '410 patent..